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TOP CITED PAPERS IN *INTERNATIONAL PSYCHOGERIATRICS*: 6a. QUALITY OF LIFE FOR PEOPLE WITH DEMENTIA LIVING IN RESIDENTIAL AND NURSING HOME CARE: THE IMPACT OF PERFORMANCE ON ACTIVITIES OF DAILY LIVING, BEHAVIORAL AND PSYCHOLOGICAL SYMPTOMS, LANGUAGE SKILLS, AND PSYCHOTROPIC DRUGS

Reflection

Context of the paper

The majority of people with dementia develop behavioral and psychological symptoms of dementia (BPSD) at some point during their illness (Jeste *et al.*, 2008). These symptoms, which are especially common among care home residents, are frequently distressing for the patients who experience them (Gilley *et al.*, 2006; Jeste *et al.*, 2008) and problematic for their professional and/or family caregivers. The starting point for our paper "Quality of life for people with dementia living in residential and nursing home care: the impact of performance on activities of daily living, behavioral and psychological symptoms, language skills, and psychotropic drugs" (Ballard *et al.*, 2001) was to try and understand the impact of BPSD, function and language skills on quality of life in care home residents with dementia. Although there were frequent statements in previous work referring to the capacity of psychiatric and behavioral symptoms to reduce quality of life, we had been unable to identify any empirical evidence to support this clinical impression in a thorough literature review. The parallel validation of Dementia Care Mapping (DCM), predominantly a practice development tool, as an observational measure of well-being/quality of life (Kitwood and Bredin, 1997; Fossey *et al.*, 2002) provided an excellent opportunity to examine this issue in a care home setting. The study focused on 209 people with dementia living in residential and nursing home care in north-east England in the U.K., who received a detailed assessment of BPSD, function and cognition. A DCM evaluation was completed for 112 of these individuals, providing a detailed observational measure of well-being, activities and social withdrawal as indices of quality of life over a six-hour daytime period. To our surprise, there was actually no association between well-being, social withdrawal or activities and BPSD. In contrast, there was a significant association between antipsychotic medication and reduced well-being, social withdrawal and activities respectively, even after controlling for the severity of behavioral disturbance. Using an arbitrary definition of "ill-being", defined as a well-being score of less than zero, 5% of people not taking antipsychotics, 10% of people taking atypical antipsychotics and 22% of people taking typical antipsychotics were defined as having ill-being. Lower levels of functional ability were also associated with significantly lower well-being, less activities and more social withdrawal. At first this latter finding appears to be contrary to one of the central principles of DCM – namely, that the assessment should be independent of dementia severity. Although high levels of well-being and engagement are possible for people with severe dementia, this probably requires higher staff numbers and a workforce with more specialized skills in order to achieve this.

Antipsychotics and quality of life

There have been eight placebo controlled trials of typical antipsychotics and 18 placebo controlled trials of atypical antipsychotics for the treatment of BPSD (Ballard and Howard, 2006; Schneider *et al.*, 2006), none of which directly measured the impact of treatment on quality of life. There had been a covert assumption that improving BPSD would automatically improve quality of life. The findings in our 2001 paper in *International Psychogeriatrics* challenged this assumption, and actually suggested that treatment with antipsychotics may have a more detrimental impact on quality of life than the symptoms for which they were prescribed. The interest in the paper has probably stemmed from this identification of an association between antipsychotic prescription and impaired quality of life in people with dementia. This does have important implications for clinical practice as the potential adverse consequences of treatment are much more difficult to justify in the absence of direct benefits in quality of life to the individual, and it provides support for the argument that the use of atypical antipsychotics should be restricted to situations where there is direct risk to the individual or others as a result of the BPSD.

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There are still very few studies that have examined the relationship between quality of life and antipsychotic drug use, particularly in the context of randomized controlled clinical trials. We have subsequently reported a small comparative trial of 48 patients suggesting improvements in the quality of life in patients with Alzheimer's disease who were switched from a typical antipsychotic to quetiapine (Ballard and Margallo-Lana, 2002). Although the limited evidence of efficacy does limit the potential value of quetiapine, this is probably helpful in indicating that atypical agents have a less detrimental impact on quality of life than typical antipsychotics. Important studies have highlighted the potential of specific non-pharmacological intervention programs to improve key outcomes such as the use of unnecessary antipsychotic drugs (Rovner *et al.* 1996; Ballard *et al.*, 2002; Fossey *et al.*, 2006), mood (Teri *et al.*, 1997; 2003) and behavioral symptoms (Cohen-Mansfield *et al.*, 2007) with person-centered training for care staff, or structured approaches such as exercise, social interaction, pleasant events or assessment of needs, but disappointingly few studies have directly evaluated the impact of these interventions on quality of life directly, or the impact of stopping antipsychotics on quality of life amongst care home residents with dementia. The Focused Intervention Training and Support (FITS) study, in a cluster randomized trial, demonstrated the capacity of a training program focused on person-centered care to significantly reduce the use of antipsychotic drugs in care homes (Fossey *et al.*, 2006). A secondary analysis of individuals participating in the FITS study who stopped antipsychotics over the course of the trial has been completed for the present paper. Over the course of the study, a consultant old age psychiatrist and a senior member of nursing staff from each home reviewed the drug prescriptions of the residents after completion of the baseline assessments and every three months over the course of the study following good practice guidelines (Howard *et al.*, 2001). DCM was used to evaluate quality of life (QoL) indices (Kitwood and Bredin, 1997), and has been shown to have good test-re-test reliability (Fossey *et al.*, 2002). The Cohen-Mansfield Agitation Inventory (CMAI; Cohen-Mansfield *et al.*, 1989) was used to measure the reported agitated and disruptive behaviors of residents. Assessments at 12 months were carried out as far as possible blind to each home's intervention: the trial staff did not identify the intervention homes to the researcher, and nursing home staff were asked not to discuss their home's intervention with the researcher. Despite these efforts, because the package was designed to influence the whole care approach of staff, it is likely that the research assistant would have been able to detect which homes had received the intervention. For the current analysis we compared changes in three QoL indices over the course of the study (social withdrawal, positive activities, well-being) between baseline and follow-up using a paired sample t test for all residents discontinuing antipsychotics over the study period. All analyses were carried out using SPSS version 15. Forty nine

Table 1. Changes in quality of life indices in residents stopping antipsychotics from the FITS trial

		FOLLOW-UP		EVALUATION (BASELINE VS FOLLOW-UP)
N = 42	BASELINE	FITS	CONTROL	
Social withdrawal	6.64 SD 8.96	−5.24 SD 13.56	−1.29 SD 5.42	T 2.1 P = 0.04*
Type 1 behaviors	+34.74 SD 19.53	+13.44 SD 23.73	+1.47 SD 24.29	T 2.3 P = 0.03*
Well-being	0.65 SD 0.69	+0.34 SD 0.59	+0.15 SD 0.98	T 2.2 P = 0.03*

FITS = Focused Intervention Training and Support. * Statistically significant, $p < 0.05$.

Table 2. Relationship of agitation and aggression with quality of life indices from the FITS trial

	SOCIAL WITHDRAWAL	WELL-BEING
Whole cohort (n = 305)		
Total CMAI	R = −0.04 P = 0.48	R = 0.02 P = 0.68
CMAI physical aggression score	R = −0.02 P = 0.73	R = −0.05 P = 0.44
Quartile with highest levels of agitation		
Total CMAI	R = 0.05 P = 0.68	R = −0.01 P = 0.91
CMAI physical aggression score	R = −0.03 P = 0.78	R = −0.15 P = 0.23

All correlations completed using Pearson's R.
FITS = Focused Intervention Training and Support; CMAI = Cohen-Mansfield Agitation Inventory.

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of these residents stopped antipsychotics between the baseline and 12-month assessments (32 FITS, 17 controls), of whom 42 were evaluated with DCM (25 FITS, 17 control). Stopping antipsychotics was associated with a significant reduction in social withdrawal, a significant improvement in well-being and a significant increase in positive activities (Table 1). This does provide some further evidence that the discontinuation of antipsychotics according to best practice guidelines does improve quality of life for people with dementia receiving these treatments. However, it is imperative that further intervention studies, both pharmacological and non-pharmacological, evaluating treatments for BPSD include a direct measure of quality of life amongst the study outcomes.

BPSD and quality of life

To take the issue full circle, it is clear from our 2001 paper that, overall, there was no significant association between BPSD and quality of life. Our clinical interpretation of this finding was that it was probably explained by the fact that the majority of BPSD are mild to moderate in severity and do not have a major impact on quality of life. This gives a clear message that treating mild-moderate BPSD with antipsychotics is unlikely to improve the quality of life of these individuals. The key question for clinical practice, however, is whether there is a small group of patients with much more severe and distressing BPSD that clearly do have a significant impact on their quality of life. From the database of the FITS study, we have also been able to examine the relationship between agitation/aggression and the key QoL indices from the baseline evaluations of 305 participants with dementia (assessments as described in the previous paragraph). We evaluated the association between BPSD and both the total score and the score for physical aggression on the CMAI. In addition we repeated the analysis selecting individuals in the highest quartile on the total CMAI (cut-off score $\geq$48) and the highest quartile for physical aggression (cut-off score $\geq$15). All evaluations were undertaken using SPSS version 15. Consistent with the findings of our 2001 paper, there was no overall association between agitation or aggression and either well-being or social withdrawal. More surprisingly, however, there was still no suggestion of an association between agitation/aggression and well-being or social withdrawal, even in the quartile with the most severe symptoms (Table 2). Clearly, there is a need to better understand the relationship between quality of life and BPSD for individuals with dementia as this is a key part of determining the optimal treatment for a particular patient and of weighing up the balances of different treatment approaches. What the current data seem to indicate is that severity of BPSD alone may not be sufficient to impact upon the quality of life of the person experiencing them, and a more careful evaluation of whether there is a specific impact on quality of life for a particular individual is probably needed. Important – but separate – issues are the impact on the quality of life of carergivers and the risk to the person or others, which also have to be balanced when making clinical treatment decisions.

In summary, our original 2001 paper highlighted a relationship between antipsychotics and quality of life, and the absence of a straightforward direct link between quality of life and BPSD. Further analysis completed as part of the current paper reinforces these conclusions. The modest progress since 2001 in understanding the relationship between BPSD and quality of life and the continuing absence of quality of life measures in BPSD treatment studies is disappointing. These are key questions to inform treatment decisions in clinical practice.

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Commentary

One of the beauties of research is that it never fails to surprise us. Often the unintended findings are the ones which influence future research directions and clinical practice more than predicted research results. One such an example is the landmark paper from Ballard and colleagues reporting the detrimental effect of antipsychotic medication on quality of life of older adults with dementia living in residential care (Ballard *et al.*, 2001). As pointed out in the above Reflection, the aim of this research was to demonstrate that behavioral and psychological symptoms of dementia (BPSD)

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directly impact on quality of life. Surprisingly, this could not be confirmed, but instead antipsychotic medication was identified as the culprit which negatively affected quality of life. It is not surprising that these findings caused this publication to be catapulted into the illustrious group of top-cited papers in *International Psychogeriatrics*. It confirmed frequent observations from clinicians and underscored widely held unease about using these drugs for treating BPSD, long before the increased risk for cerebrovascular events for the same group of drugs and patients made the headlines. It is exciting that Ballard and colleagues in their reflection now present additional new data confirming their 2001 findings and even going one step further to report improved quality of life in patients with dementia for whom antipsychotic medication could be stopped.

The puzzling question remains why the presence of BPSD does not seem to impact directly on quality of life even in the more severe forms. It seems to act as a reminder that BPSD are complex clinical phenomena about which our knowledge is still very limited. However, surprising research results often trigger creativity to look at a problem from a new, in this case more pragmatic, angle. The findings from Ballard and colleagues might suggest that a way forward is to focus next on what types of intervention can directly improve quality of life in residents and carers of residential care facilities (e.g. stopping antipsychotic medication).

Well-performed clinical studies with a large enough sample size to provide meaningful results in this area of psychogeriatrics were rare in 2001 and are still rare in 2009. This highlights the ongoing challenges involved in conceptualizing a feasible research plan and then of securing adequate funding to conduct the research in residential care facilities which, in many countries, struggle to maintain good quality dementia care due to financial limitations as well as the heavy burden of time constraints on overworked and underpaid staff. The findings of Ballard and colleagues, as well as the additional results presented in their Reflection above, should remind us that the community of researchers and clinicians working in psychogeriatrics needs to continue to lobby both for more support for research and for improved clinical care for the benefit of those with dementia and those caring for them.

No doubt, for the time being, antipsychotic drugs will continue to have their place in clinical scenarios where they are needed to manage acute risk to the patient or those providing care. However, the mounting evidence that antipsychotic medications have many harmful consequences when given to patients with dementia should encourage researchers, as well as funding agencies, to focus on exploring non-pharmacological interventions which are suitable for use in residential care. The move away from antipsychotic medications, which too often are considered a "quick and easy fix" to manage difficult behavior, especially in acute hospital settings but also in residential care, and to replace them with effective and safe non-pharmacological interventions requires a paradigm shift for everyone involved in dementia care. The paper by Ballard *et al.* (2001) was crucial to get us on the right track.

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